

161-1655  
Atty. Dkt. No. 048331-1707

JUN 10 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2300

Applicant: Tabor, et al.

Title: ISOTHERMAL AMPLIFICATION  
OF DNA

Appl. No.: ~~09/480,878~~ 10/013693

Filing Date: 11/06/2003

Examiner:

Art Unit:

<b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: <b>Commissioner for Patents</b> , PO Box 1450, Alexandria, Virginia 22313-1450, on the date below.  <u>Diane Garcia</u> (Printed Name)  <u>Diane Garcia</u> (Signature)  <u>June 1, 2004</u> (Date of Deposit)
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**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without*

*Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

#### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

#### **RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even

entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit  
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Respectfully submitted,

Date 12 January 2004

By Wesley B. Ames

FOLEY & LARDNER

Customer Number: 30542

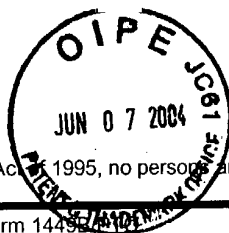
Telephone: (858) 847-6714

Facsimile: (858) 792-6773

Wesley B. Ames

Attorney for Applicant

Registration No. 40,893



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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Filed on June 1, 2004

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Application Number	09/480,878
Filing Date	11/07/2003
First Named Inventor	Stanley Tabor
Group Art Unit	1655
Examiner Name	
Attorney Docket Number	048331-1707

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Sheet 1 of 7

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,942,130		Tabor et al.	07-17-1990	
	A2	4,946,786		Tabor et al.	08-07-1990	
	A3	5,194,370		Berninger et al.	03-16-1993	
	A4	5,556,772		Sorge et al.	09-17-1996	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A5	EP	0623682 AI		Becton, Dickinson and Company			
	A6	WO	00/41524		President and Fellows of Harvard College			
	A7	WO	96/05296		Institut for Molekulare Biotechnologie, E.V.			
	A8	WO	98/42689		Bayer Aktiengesellschaft			

**NON PATENT LITERATURE DOCUMENTS**

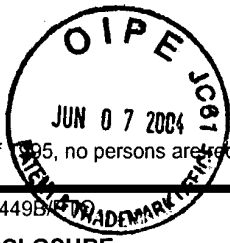
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	A9	Almaula et al., "Nucleoside Dephosphate Kinase From Escherichia Coli," J. Bact. 177:2524 (1995)	
	A10	Applegren et al., "Further characterization of the human cell multiprotein DNA replication complex." Journal Of Cellular Biochemistry 59:91-107 (1995).	

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Sheet 2 of 7

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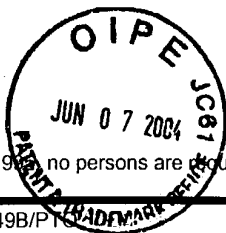
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	A11	Barnes, "PCR Amplification Of Up To 35-Kb DNA With High Fidelity And High Yield From Bacteriophage Templates," Proc. Natl. Acad. Sci. USA 91:2216 (1994)	
	A12	Beato, "Steroid hormone receptors: Many actors in search of a plot." Cell, 83:851-857, 1995	
	A13	Bernstein et al., "A 7-kDa Region Of The Bacteriophage T7 Gene 4 Protein Is Required Of Primase But Not For Helicase Activity," Proc. Natl. Acad. Sci. USA 85:396 (1988).	
	A14	Bernstein et al., "Characterization Of The Helicase And Primase Activities Of The 63-Kda Component Of The Bacteriophage T7 Gene 4 Protein," J. Biol. Chem. 264:13066 (1989)	
	A15	Blanco et al., "Terminal Protein -Primed DNA Amplification," Proc. Natl. Acad. Sci. USA 91:12198-12202, December (1994)	✓
	A16	Cheng et al., "Effective Amplification Of Long Targets From Cloned Insects And Human Genomic DNA", Proc. Natl. Acm). Sci. USA 91:5695 (1994)	✓
	A17	Cohen et al., "An Artificial Cell Cycle Inhibitor Isolated From A Combinatorial Laboratory," Proc. Natl. Acad. Sci. USA 95:14272 (1998)	✓
	A18	Doherty et al., "Bacteriophage T7 DNA ligase." J. Biol. Chem. 271:11083 (1996)	✓
	A19	Engler et al., "Bacteriophage T7 Dna Replication," J. Biol. Chem. 258:11197 (1983)	✓
	A20	Engler et al., "Two Forms Of The DNA Polymerase Of Bacteriophage T7," J. Biol. Chem. 258:11165-11173 (1983).	

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**NON PATENT LITERATURE DOCUMENTS**

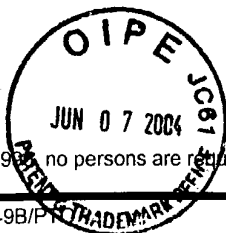
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	A21	Evans, The steroid and thyroid hormone receptor superfamily. Science, 240: 889-895, 1988.	✓
	A22	Ewing et al., "Base-Calling Of Automated Sequencer Traces Using Phred. II. Error Probabilities," Genome Research 8:186 (1998)	✓
	A23	Famulok et al., Oligonucleotide libraries – variatio delectat. Curr. Opin. Chem. Biol. 2:320 (1998)	✓
	A24	Gibson et al., "A Novel Method For Real Time Quantitative RT-PCR," (Genome Research 6:995 (1996)	✓
	A25	Greenstein et al., "Interaction Between The Replication Origin And The Initiator Protein Of The Filamentous Phage FI: Binding Occurs In Two Steps," J. Molec. Biol. 197:157 (1987)	✓
	A26	Guatelli et al., "Isothermal, In Vitro Amplification Of Nucleic Acids By A Multienzyme Reaction Modeled After Retro Viral Replication," Proc. Natl. Acad. Sci. USA 87:1874 (1990)	✓
	A27	Guo et al., "The Linker Egon Between The Helicase And Primase Domains Of The Bacteriophage T7 Gene 4 Protein Is Critical For Hexamer Formation," J Biol. Chem. 274:30303 (1999)	✓
	A28	Harth et al., "Bacteriophage Fd Gene-2 Protein," Eur. J. Biochem. 119:663 (1981)	✓

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Sheet 4 of 7

**NON PATENT LITERATURE DOCUMENTS**

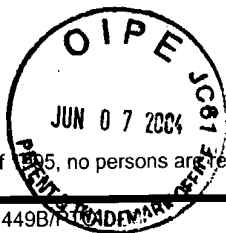
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	A29	Higashitanit et al., "A Single Amino Acid Substitution Reduces The Superhelicity Requirement Of A Replication Initiator Protein," Nucl. Acids Res. 20:2685 (1992)	✓
	A30	Jesperon, T. et al., "Efficient Non-PCR-Medicated Overlap Extension Of PCR-Medicated Overlap Extension of PCR Fragments By Exonuclease "End Polishing", Biotechniques 23, No. 1:48-52 (1997)	✓
	A31	Kerr et al., "Gene 6 Exonuclease Of Bacteriophage T7," J Biol. Chem. 247:305 (1972)	✓
	A32	Kim et al., "Purification And Characterization Of The Bacteriophage T7 Gene 2.5 Protein," J. Biol. Chem. 267:15022 (1992)	✓
	A33	Lee et al., "Coordinated Leading And Lagging Strand DNA Synthesis On A Minicircular Template," Mol. Cell. 1:1001 (1998)	✓
	A34	Lohman et al., "Large Scale Overproduction And Rapid Purification Of The Escherichia Coli SSB Gene Product. Expression Of The SSB Gene Under PL Control," Biochemistry*	✓
	A35	Mangelsd and Evans, "The RXR heterodimers and orphan receptors. Cell, 842-850.	✓
	A36	Mendelman et al., "Evidence For Distinct Primase And Helicase Domains In The 63-KDA Gene 4 Protein Of Bacteriophage T7," J.Biol.Chem 268:27208 (1993)	✓

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Sheet 5 of 7

**NON PATENT LITERATURE DOCUMENTS**

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	A37	Matson and Richardson, "DNA-Dependant Nucleoside 5'- Triphosphatase Activity Of The Gene 4 Protein Of Bacteriophage T7," J Biol Chem. 258:14009-14016 (1983)	✓
	A38	Mendelman et al., "Roles Of Bacteriophage T7 Gene 4 Proteins In Providing Primase And Helicase Functions In Vivo," Proc. Natl. Acad. Sci. USA 89:10638 (1992)	✓
	A39	Meyer et al., "Replication Of Phage FD RF With FD Gene 2 Protein And Phage TF Enzymes," J. Biol. Chem. 256:58 10 (1981)	✓
	A40	Mitra and Church, "In Situ Localized Amplification And Contact Replication Of Many Individual DNA Molecules," Nucleic Acids Res. 27 (24):E34 (1999)	✓
	A41	Notarnicola et al., "A Domain Of The Gene 4 Helicase/Primase Of Bacteriophage T7 Required For The Formation Of An Active Hexamer," J. Biol. Chem 273:5260 (1998)	✓
	A42	Notarnicola et al., "The Nucleotide Binding Site Of The Helicase/Primase Of Bacteriophage T7," J. Biol. Chem. 268:27198 (1993)	✓
	A43	Park et al., "Formation Of A DNA Loop At The Replication Fork Generated By Bacteriophage T7 Replication Proteins," J. Biol. Chem. 273:5260 (1998)	✓
	A44	Saiki et al., "Enzymatic Amplification Of B-Globin Genomic Sequences And Restriction Site Analysis For Diagnosis Of Sickie Cell Anemia," Science 230:1350-1354 (1985)	✓

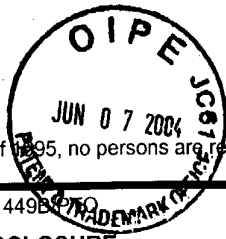
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	A45	Saiki et al., "Primer-Directed Enzymatic Amplification Of DNA With A Thermosable DNA Polymerase," Science 239:487-491 (1988)	✓
	A46	Salas, "Protein Priming Of DNA Replication," Ann. Rev. Biochem 60:39 (1991)	✓
	A47	Sarkar et al., "Removal of DNA contamination in polymerase chain reaction reagents by ultraviolet irradiation." Methods Of Enzymology, 218:38 1-388 (1993)	
	A48	Scherzinger et al., "Role Of Bacteriophage T7 DNA Primase In The Initiation Of DNA Strand Synthesis," Nucl. Acids Res. 4:4151 (1977)*	
	A49	Scherzinger et al., "Bacteriophage-T7-induced DNA-priming protein : A novel enzyme involved in DNA replication. Eur. J. Biochem 72:543-558 (1977).	
	A50	Tabor et al., "Eschericia Coli Thioredoxin Confers Processivity On The Dna Polymerase Activity Of The Gene 5 Protein Of Bacteriophage T7," J. Biol. Chem. 262:16212-16223 (1987)	
	A51	Tabor et al., "Selective Inactivation Of The Exonuclease Activity Of Bacteriophage T7 DNA Polymerase By In Vitro Mutagenesis," J. Biol. Chem. 262:6447-6458 (1989)	
	A52	Tabor et al., "DNA Sequence Analysis with a Modified Bacteriophage T7 DNA Polymerase." Journal Of Biological Chemistry 265(14):8322-8328 (1990)	

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A53	Tyagi et al., "Extremely Sensitive Background-Free Gene Detection Using Binary Probes And QB Replicase," Proc. Natl. Acad. Sci. USA 93:5395 (1996)	
	A54	Walker et al., "Isothermal In Vitro Amplification Of DNA By A Restriction Enzyme/DNA Polymerase System," Proc. Natl. Acad. Sci. USA 89:392 (1992)	
	A55	Werle, <u>Laboratory Methods For The Detection Of Mutations And Polymorphisms In DNA</u> , ed. Taylor "Direct Sequencing of Polymerase chain reaction products." pp. 163-174 (1997)	
	A56	Zhang et al., "Amplification Of Target-Specific, Ligation-Dependant Circular Probe," Gene 211:277 (1998)	

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